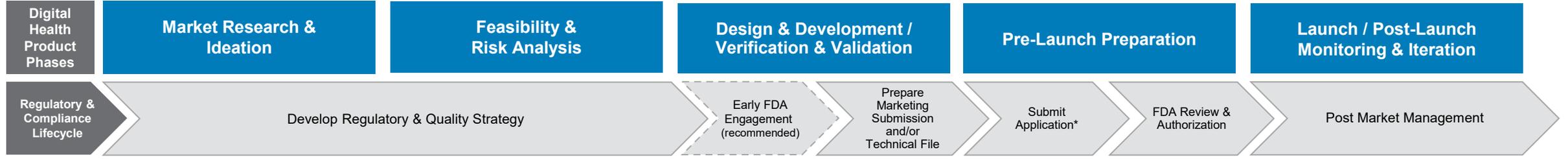


# FDA Resource Index for Digital Health Device Innovators

Tools, engagement opportunities and guidance to help you through all phases of the total product life cycle



FDA Resources listed by most relevant phase, though they may be used throughout the iterative product lifecycle

Digital Health Product Phases	Market Research & Ideation	Feasibility & Risk Analysis	Design & Development / Verification & Validation	Pre-Launch Preparation	Launch / Post-Launch Monitoring & Iteration		
Regulatory & Compliance Lifecycle	Develop Regulatory & Quality Strategy		Early FDA Engagement (recommended)	Prepare Marketing Submission and/or Technical File	Submit Application*	FDA Review & Authorization	Post Market Management
Available FDA Resources	<p><b>Digital Health Policy Navigator</b> Determine which software functions are the focus of FDA's oversight </p> <p><b>Digital Health FAQs</b> Get answers to frequently asked questions </p> <p><b>Device Advice</b> Read regulatory information about medical devices and ask questions </p> <p><b>CDRH Learn</b> Watch learning modules on medical device regulation </p> <p><b>Patient-Centered Development</b> Learn how to include patients during medical device development </p> <p><b>Digital Health Inbox</b> Get informal answers to your digital health policy questions </p>	<p><b>Medical Device Software Guidance Navigator</b> Identify digital health guidances for your regulatory strategy </p> <p><b>Digital Health Guidances</b> Get clarity on the FDA's regulation of digital health products </p> <p><b>Regulatory Science Tools</b> Get support for medical device development </p> <p><b>Quality System &amp; Good Manufacturing Practices</b> Learn about requirements &amp; standards </p> <p><b>Small Business Assistance</b> Get support for small innovators and ask questions </p>	<p><b>Q-Submission Program</b> Optional opportunity to request feedback and meetings for medical device submissions </p> <ul style="list-style-type: none"> <li>Informational Meeting</li> <li>Pre-Submission</li> </ul> <p><b>Request for Information 513(g)*</b> Request information about classification or requirements applicable to a device </p> <p><b>Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions</b> Learn about supporting safety &amp; effectiveness in AI-enabled devices that modify over time </p>	<p><b>Content of Premarket Submissions for Device Software Functions</b> Get information regarding the recommended documentation for premarket submissions </p> <p><b>eSTAR Program</b> Receive guidance through the process of preparing a comprehensive medical device submission with this interactive PDF form </p> <p><b>Types of Communication During the Review of Medical Device Submissions</b> Review forms of formal communication and interactive review </p> <p><b>Early Orientation</b> Engage with the FDA on marketing submissions for medical device software </p>	<p><b>MedWatch</b> Use our Safety Information &amp; Adverse Event Reporting program for patients, healthcare professionals &amp; consumers </p> <p><b>Device Registration and Listing*</b> Register annually with the FDA </p> <p><b>Deciding When to Submit a 510(k) for a Software Change to an Existing Device</b> Review the decision-making process </p> <p><b>Medical Device Recalls</b> Stay informed on medical device recalls and early alerts </p>		

Innovator Tool  
 FDA Engagement Opportunity  
 Guidance  
 \* FDA Associated Fee